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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,034	09/22/2003	Rainer Bosse	33544/US	1433

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David E. Bruhn  
DORSEY & WHITNEY LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/668,034

Applicant(s)

BOSSE ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 3763

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges amended claim 1, and currently claims 1-17 are pending for examination.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection based on Applicant's amended independent claim.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) that was submitted on 9/22/2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12, and 16-17 are rejected under 35 U.S.C 102(b) as being anticipated by Vaillancourt (5,591,138). Vaillancourt discloses a protected safety needle assembly.

Art Unit: 3763

Regarding claims 1 and 2, Vaillancourt discloses a cannula cover that can be axially retracted prior to injection to expose the cannula (Figure 1). A latch system that can be unlatched by cover rotation protects the assembly (Figure 1).

Regarding claims 3-6, and 12, Vaillancourt discloses a cannula with a seal that allows for the passage of the cannula, comprising two tongues, sealing sections, and is forced open by movement of the cover (Figures 9-10).

Regarding claims 16-17, Vaillancourt discloses a latch mechanism (Figure 1) and a sealing element that exposes the cannula when it is opened (Figures 9-10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-11 are rejected under 35 U.S.C 103(a) as being unpatentable over Vaillancourt in view of Galli (5,681,291). Vaillancourt meets the claim limitations as described above but does not include the seal sliding away from the cannula opening.

Regarding claims 7-11, Galli discloses a sealing strip that is slid from the cannula passage opening by a slider that is on the cover (see figures 1-10) in order to make exposing the cannula.

It would have been obvious to one of ordinary skill in the art to modify Vaillancourt with Galli and utilize a slider that removes a sealing strip from the cannula opening in order to quickly and simply expose the cannula as taught by Galli.

***Claim Rejections - 35 USC § 103***

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt in view of Foster (6,217,559). Vaillancourt discloses the claimed invention as discussed above. However, Vaillancourt does not teach the use of a threaded insert either the cover or threaded insert.

Regarding claims, 13-15, Foster discloses a syringe with a threaded cover that moves axially (Figures 1-4).

It would have been obvious to one of ordinary skill in the art to modify the cannula system of Vaillancourt and with the threaded arrangement of Foster in order to securely mount the axial sheath for easy rotational movement. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Foster.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3763


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on Monday through Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/20/06  
[Date]

  
NICHOLAS LUCCHESI  
SUPERVISOR  
10/668,034

  
Christopher Koharski  
Examiner  
Art Unit 3763